60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20150004A **DATE:** 1 September 2015

PROTOCOL TITLE: Creation of chronic myocardial infarction in a pig (*Sus scrofa*) model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Maj Lucas Neff, Dr. Douglas Boyd

DEPARTMENT: General Surgery **PHONE #:** 423-5224

INITIAL APPROVAL DATE: 20 November 14 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: Surgeon General

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	68	42	42

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
_X__ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
___ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	_X__ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C _X__ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X__ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	3 April 2015	Animal Care
2	21 May 2015	Personnel

6. **FUNDING STATUS:** Funding allocated: $ Funds remaining: $ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? _X_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Maj Lucas Neff (PI) IACUC Approval-Yes

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

Lt Col Daren Danielson (PI) 21 May 2015

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

Hanes DW, Wong ML, Chang CW, Humphrey S, Grayson JK, Boyd WD, Griffiths LG. Embolization of the first diagonal branch of the left anterior descending coronary artery as a porcine model of chronic transmural myocardial infarction. J Transl Med 2015;13:187-200.

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes. This protocol demonstrated that close cooperation between the DGMC CIF and UC Davis was possible and provided valuable training opportunities for residents.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: The goal of this protocol was to create myocardial infarctions in mini-pigs using polystyrene microspheres to Infarct a portion of the left ventricle myocardium for future regenerative medicine studies. Methods: Castrated male Yucatan mini pigs were pre-medicated with oral amlodarone, aspirin, and clopidogrel according to protocol. Once the pigs were anesthetized a baseline echocardiogram was obtained. Under fluoroscopic guidance, a hockey stick catheter was placed in a femoral artery into the left anterior descending (LAD) coronary artery. A guide wire was then placed in the first or second diagonal branch of the LAD, over which a coronary artery balloon catheter was advanced. Once in place, the balloon catheter was inflated and polystyrene microspheres were injected to occlude the vessel. The echocardiogram was repeated, and the pigs were recovered. Two weeks later, provided there were no postoperative complications. The pigs were transferred to UC Davis for maintenance and further surgery.

Results: Forty-two pigs underwent myocardial infarctions without misadventure. Infusion of polystyrene beads into a diagonal branch of the LAD resulted in a repeatable and controlled myocardial infarction.
Conclusion: The method reported here provided consistent and repeatable myocardial infarcts with minimal morbidity.

(PI / TC Signature) (Date) 12 Nov 2015

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission (Mandatory)

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: The goal of this protocol was to create myocardial infarctions in mini pigs using polystyrene microspheres to infarct a portion of the left ventricle myocardium for future regenerative medicine studies.
Methods: Castrated male Yucatan mini-pigs were pre-medicated with oral amiodarone, aspirin, and clopidogrel according to protocol. Once the pigs were anesthetized a baseline echocardiogram was obtained. Under fluoroscopic guidance, a hockey stick catheter was placed in a femoral artery into the left anterior descending (LAD) coronary artery. A guide wire was then placed in the first or second diagonal branch of the LAD, over which a coronary artery balloon catheter was advanced. Once in place, the balloon catheter was inflated and polystyrene microspheres were injected to occlude the vessel. The echocardiogram was repeated, and the pigs were recovered. Two weeks later, provided there were no postoperative complications, the pigs were transferred to UC Davis for maintenance and further surgery.
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Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**